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NOTICE OF ALLOWANCE AND FEE(S) DUE

27777

7590

03/11/2010

PHILIP S. JOHNSON
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NEW BRUNSWICK, NJ 08933-7003

EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 03/11/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,843	12/10/2003	Chris Cicenias	END5007USNP	6679

TITLE OF INVENTION: BIOPSY DEVICE WITH SAMPLE TUBE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	06/11/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop **ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the **ISSUE FEE** and **PUBLICATION FEE** (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

27777 7590 03/11/2010

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop **ISSUE FEE** address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/732,843 12/10/2003 Chris Cienas END5007USNP 6679

TITLE OF INVENTION: BIOPSY DEVICE WITH SAMPLE TUBE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	06/11/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
NGUYEN, HUONG Q	3736	600-564000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number** is required.

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY AND STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims **SMALL ENTITY** status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming **SMALL ENTITY** status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____
 Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.**

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PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			NGUYEN, HUONG Q	
			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 03/11/2010				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 236 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 236 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.

10/732,843

Examiner

HELEN NGUYEN

Applicant(s)

CICENAS ET AL.

Art Unit

3736

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 23 February 2010.
2. ☒ The allowed claim(s) is/are 1-9,11-13,16-18 and 20-23.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 2/23/2010
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736

EXAMINER'S AMENDMENT

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 2/23/2010 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Oath/Declaration

2. Please note the new oath submitted for Beth McCombs on 2/12/2010 to rectify the Printer Rush dated 12/31/2009.

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gerry Gressel on 11/25/2009.

The application has been amended as follows:

Claim 1

A biopsy device comprising:

a hollow biopsy needle having a tissue receiving port;

a hollow cutter advanceable within the biopsy needle to sever tissue received within the tissue receiving port, wherein the cutter has a sidewall surrounding an interior, wherein the cutter has a plurality of holes spaced from the distal end of the cutter, wherein the plurality of holes are formed transversely through the sidewall of the cutter for providing fluid communication from a region exterior to the sidewall of the cutter to the interior of the cutter, and wherein the holes are positioned for providing vacuum axially through the cutter when multiple tissue samples are disposed within ~~the~~ a sample tube within the cutter; and

~~a~~ the sample tube advanceable within the hollow cutter, the sample tube having an open distal end sized for receiving a tissue sample severed by the hollow cutter a the sample tube being releasably supported on the biopsy device such that the sample tube and at least one tissue sample stored therein may be removed from the biopsy device without disassembling the biopsy device, ~~and~~ wherein the sample tube comprises a vacuum lumen and a sample lumen, ~~and~~ wherein the vacuum lumen extends along side of at least a portion of the sample lumen ((.)) a

wherein the hollow cutter is operable to be advanced to a distal most position within the hollow biopsy needle to sever the tissue sample, and

wherein the sample tube is operable to be advanced to the distal most position within the hollow cutter to receive the tissue sample after the tissue sample has been completely severed,

Claim 7

The biopsy device of Claim 1 comprising an apparatus for advancing and retracting the cutter within the biopsy needle.

Claim 8

The biopsy device of Claim 7 comprising an apparatus for advancing and retracting the sample tube within the cutter.

Claim 16

A biopsy device comprising:

a hollow biopsy needle having a closed distal end and a lateral tissue receiving port spaced proximally of the closed distal end;

a hollow cutter having an open distal end, a lumen extending proximally from the open distal end, and a plurality of holes extending through a wall of the cutter; ~~and~~ the cutter advanceable to a distal most position within the biopsy needle to sever tissue received within the tissue receiving port;

a sample tube having an open distal end defining a distal opening, the sample tube being releasably supported on the biopsy device, and the sample tube advanceable within the cutter;

a drive mechanism for advancing and rotating the cutter within the biopsy needle((,)) ;
and

a sample tube advancement assembly, wherein the sample tube advancement assembly is operable to advance the sample tube ~~distally~~ to the distal most position within the cutter to store a tissue sample within the sample tube after the cutter has been advanced within the needle to the distal most position to sever the tissue sample ((;)) ; wherein the sample tube comprises a vacuum lumen and a sample lumen, and wherein the vacuum lumen extends along side of at least a portion of the sample lumen.

Claim 17

A method of obtaining a tissue sample comprising the steps of:

drawing tissue into a side tissue receiving port of a hollow biopsy needle;

advancing a hollow cutter in the needle to sever a tissue sample and to encapsulate the severed tissue sample within the cutter upon reaching a distal most position in the hollow biopsy needle, wherein the cutter closes the tissue receiving port when the cutter is at the distal most position;

advancing a hollow sample tube to the distal most position in the cutter to position the tissue sample in the sample tube, wherein the hollow sample tube has an open distal end, wherein the open distal end comprises a distally facing opening defined by the distal most perimeter of the open distal end, wherein the tissue sample is axially received in the hollow sample tube through the opening at the open distal end of the hollow sample tube during the act of advancing the hollow sample tube, wherein at least a portion of the act of advancing the hollow sample tube is performed after the cutter has reached the distal most position and after the cutter has encapsulated the severed tissue sample; and

wherein the sample tube comprises a vacuum lumen and a sample lumen, wherein the vacuum lumen extends along side of at least a portion of the sample lumen;

and wherein the method comprises providing vacuum to the sample tube vacuum lumen.

Claim 23

A needle assembly comprising a hollow biopsy needle having a closed distal end having a tissue piercing tip and a side tissue receiving port spaced proximally of the closed distal end, a

cutter lumen, and a vacuum lumen, and wherein the needle comprises an axially extending slot positioned proximal of the side tissue receiving port, the axially extending slot communicating between the cutter lumen and the vacuum lumen;

a hollow cutter advanceable within the biopsy needle to sever tissue received within the tissue receiving port, wherein the cutter has a sidewall surrounding an interior, wherein the cutter has an open distal end and plurality of holes spaced from the distal end of the cutter, wherein the plurality of holes are formed transversely through the sidewall of the cutter for providing fluid communication from a region exterior to the sidewall of the cutter to the interior of the cutter;
~~and~~

a sample tube advanceable within the hollow cutter, the sample tube having an open distal end sized for receiving a tissue sample severed by the hollow cutter, the sample tube being releasably supported on the biopsy device such that the sample tube and at least one tissue sample stored therein may be removed from the biopsy device without disassembling the biopsy device; and

a vacuum source operable to communicate vacuum through the sample tube ((.)) ,
wherein the hollow cutter is operable to be advanced to a distal most position within the hollow biopsy needle to sever the tissue sample, and
wherein the sample tube is operable to be advanced to the distal most position within the hollow cutter to receive the tissue sample after the tissue sample has been completely severed.

Also, please cancel **Claim 19**.

4. The following is an examiner's statement of reasons for allowance: the prior art does not teach of suggest alone or in combination a biopsy device comprising a hollow biopsy needle, a hollow cutter, and a hollow sample tube, wherein the hollow cutter is operable to be advanced to a distal most position within the hollow biopsy needle to sever the tissue sample, and wherein the sample tube is operable to be advanced to the distal most position within the hollow cutter to receive the tissue sample after the tissue sample has been completely severed.
5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736